

DETAILED ACTION

Status of the Claims

Following the Reply filed on January 27, 2011, claims 1-9, 11-14 and 20-25 are pending.

Claims 1, 4, 9, 13, 14 and 20-22 have been amended. New claims 23-25 have been added.

Previous Grounds of Rejection are Withdrawn

The rejection of claims 1-8, under 35 U.S.C. 102(b), as being anticipated by (QLT) WO 03/039597 A1, published May 15, 2003 is withdrawn in view of applicants' amendments to the claims.

The rejection of claims 13 and 14, under 35 U.S.C. 103(a) as being unpatentable over QLT in view of Kalka "Photodynamic therapy in dermatology", (J Am Acad Dermatol. 389-413, Mar. 2000) is withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1-9, 11, 12 and 20-22 under 35 U.S.C. 103(a) as being unpatentable over QLT in view of (Clement) US Published Application 2004/0166129, published August 26, 2004, is withdrawn in view of applicants' amendments to the claims.

Claim Rejections - 35 USC § 103 New Grounds of Rejection – Necessitated by Amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 13-14 and 20-23 are obvious over QLT in view of Kalka and Khaiat

Claims 1-8, 13-14 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT in view of Kalka and (Khaiat), US Published Application 2004/0228885 published November 18, 2004.

Applicants' amended claim 1 discloses a method to treat acne vulgaris in a subject in need thereof, which method comprises:

- (i) topically applying a composition comprising a green porphyrin photosensitizer and solubilizer to skin tissue of said subject exhibiting symptoms of acne, and
- (ii) exposing the tissue to energy at a wavelength capable of activating the photosensitizer,
wherein steps (i) and (ii) are repeated until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment.

Claims 2 and 3 (both dependent on claim 1) disclose, respectively: wherein the photosensitizer is selected from verteporfin, lemuporfin, and combinations thereof; and wherein the composition has a viscosity at 20 °C of from about 50 cps to about 50000 cps.

Claim 8 (dependent on claim 1) discloses said method wherein steps (i) and (ii) are repeated until the number of acne lesions has been reduced by 30% or more.

Amended claim 4 discloses a method to treat acne vulgaris in a subject in need thereof, which method comprises:

- (i) topically applying a composition comprising at least one photosensitizer to skin tissue of said subject exhibiting symptoms of acne,

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(ii) removing excess composition from the skin, and
(iii) exposing the tissue to energy at a wavelength capable of activating the photosensitizer,
wherein steps (i), (ii), and (iii) are repeated until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment.

Claims 5-7 (dependent on claim 4) disclose respectively:

- where the photosensitizer is a green porphyrin (claim 5);
- wherein the photosensitizer is selected from verteporfin, lemuporfin, and combinations thereof (claim 6);
- wherein the excess composition is removed by wiping with dry cloth, wiping with a moist towelette, washing with alcohol, washing with a soap free cleanser, washing with a mild shampoo, or combinations thereof (claim 7).

Applicants' claim 13 discloses a method to treat acne vulgaris in a subject in need thereof, which method comprises:

(i) topically applying a composition comprising a green porphyrin and skin-penetration enhancer to skin tissue of said subject exhibiting symptoms of acne, and
(ii) exposing the tissue to light supplied by a light emitting diode device wherein the device comprises LED's emitting red light and LED's emitting blue light
wherein steps (i) and (ii) are repeated until the number of acne lesions has been reduced by 10% or more, as compared to the number of acne lesions prior to treatment.

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because the teachings of QLT, Kalka and Khaiat, are directed towards applicants' invention of claims 1-8, 13-14 and 20-23.

Similar to applicants' claims 1-8, QLT teaches treatment of acne (page 14, lines 22-26, claim 13 and 14) comprising administration of a photosensitizing agent, such as green porphyrins (page 3, line 30 through page 6) such as the preferred BPD-MA (vertepofrin) (page 4, lines 15-18) and QLT0074 (lemuporfin) (page 6, lines 4-7) and comprising administering a light energy to activate the photosensitizer at the target tissue (page 2, lines 10-23). The solubilizer of instant claim 1 is taught by QLT in that the solubilizer aids in hydrophobic photosensitizers and are also penetration enhancers (page 9, line 30 to page 10, line 25). QLT

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reads upon claims 2, 5 and 6 with its teaching of green porphyrins photosensitizers (verteporfin and lemuporphin). QLT reads upon applicants' claim 3 where it teaches the preferred compositions to have a viscosity at 20 C of from about 50 cps to about 50000 cps (page 9, lines 24-25). QLT reads upon applicants claim 4 and claim 7 by teaching the removal of excess photosensitizer, which might otherwise mask the target, preventing the activation energy from reaching the target (page 13, lines 7-11).

QLT is silent with regard to the reduction of percentage of acne lesions and repeated treatments with acne, however, it would be routine for one of ordinary skill in the art to apply the acne treatment multiple times in order to reach desired percentages of acne lesion reduction such as 10%, 20% or 30%, reading upon applicants' claims 1, 4, 8, 13 and 23-25.

Kalka teaches that diode lasers are employed to produce red light in the range of 770 to 850 nm (page 395, column 1) and teaches that photodynamic management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound (page 394, column 2). Similarly to Kalka, QLT teaches use of any suitable light source to activate the photosensitizer (page 1, lines 9-14) and teaches that photosensitizers generally absorb radiation in the range of from about 400 nm (about the range of blue light) to about 800 nm (about the range of red light) (page 3, lines 14-16). Thus, Kalka's teaching of diode lasers to produce red light in the range of 770 to 850 nm reads upon applicants' claims 13 and 14.

Furthermore, while QLT does not exemplify the routine use of repeating acne treatments and subsequently measuring the reduction % of acne lesions, this deficiency is corrected by Kalka. Kalka teaches "**repeated** illumination with blue light at a cumulative dose of 325 J/cm² resulted in **marked reduction** of both **acne** and seborrhea" (page 403, column 2, second

paragraph). Kalka teaches repeated acne treatment within the scope of applicants' invention and notes the marked reduction (which can be measured as a percentage reduction) of acne, thus reading upon those particular limitations found in applicants' claims 1, 4, 8, 13 and 23-25.

Khaiat teaches that multiple, repeat treatments (paragraph 0079) of acne over a period of weeks results in percent reductions of said acne (Figures 1-6 and paragraphs 0013-0018, Tables 2A, 2B, 3 and 4). Thus, Khaiat bolsters the teaching of Kalka that repeated acne treatments results in a percent reduction of acne lesions, as disclosed by applicants' limitations of claims 1, 4, 8, 13 and 23-25.

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht*, 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 9, 11 and 12 are obvious over QLT in view of Kalka, Khaiat and Clement

Claims 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over QLT in view of Kalka, Khaiat and Clement.

The teachings of QLT, Kalka, Khaiat and Clement are discussed above and are hereby incorporated herein. As these claims ultimately depend on claim 1, it is pointed out that the teachings of claim 1 above are also incorporated herein. Clement teaches treatment of acne vulgaris comprising the use of retinoids with illuminating radiation (paragraph 6).

Applicants' claims 9 and 11 are directed towards a method of treating acne as per claim 1 with the further disclosure that at least one non-photodynamic therapy (e.g. retinoid) is administered. Claim 12 exemplifies said non-photodynamic therapy as being a retinoid.

Claims 9, 11 and 12 depend upon claim 1. The method of claim 1 is rendered obvious over QLT, Kalka and Khaiat as discussed above. As such the teachings of Clement that a non-photodynamic therapy (retinoid), when combined with QLT, Kalka and Khaiat, read upon applicants' claims 9, 11 and 12 that disclose a non-photodynamic acne therapy (retinoid) combined with the photodynamic acne treatment of claim 1.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80,440 F.2d 442,445, 169 USPQ 423,426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21,279 F.2d 274,276-77,126 USPQ 186,188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention as claimed because the teachings of QLT, Kalka and Khaiat and Clement are directed towards applicants' invention of claims 9, 11 and 12.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

In summary, no claims are allowed.

Applicants' amendment necessitated the new grounds of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If applicant should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in *ipsis verbis*, clarification on the record may be helpful). Should

Applicant present new claims, Applicant should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM LEE whose telephone number is (571)270-3876. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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